• No conflicts to disclose
• Some products discussed are not FDA approved for all pediatric patients
Question

• A 14 year old male patient calls you because his sugar is 478 mg/dL. He was diagnosed with Type 1 Diabetes four years ago and currently uses an insulin pump. His last A1c in clinic was 7.6%. He cannot figure out why his sugar is high and won’t come down because he feels he is doing everything as usual. He feels fine with no symptoms.

• What is the most likely issue?
• What is the intervention?
• What might happen without the intervention?
Diabetes Technology Timeline

• 1920’s:
  • Insulin

• 1970’s:
  • first pumps

• 1980’s:
  • Insulin pens
  • recombinant human insulin

• 1990’s:
  • Insulin pumps become readily available
  • Rapid acting insulin

• 2000’s:
  • Long acting insulins
  • Sensors

• Now:
  • Commercial integrated pump/sensor products
  • Smart phone app integration
What’s new in Diabetes Technology?

• Interoperable Insulin Pump (2/14/19)

• Implantable Continuous Glucose Monitoring System (6/6/19)

• New glucagon formulations
  • 6/24/19: Baqsimi intranasal glucagon
  • 7/24/19: Gvoke prefilled pen

• iLet (insulin + glucagon closed loop system) gets breakthrough device recognition from FDA (12/10/19)
Glucose Sensors
Continuous Glucose Sensors

Libre
Change sensor every 14 days

Dexcom
Change sensor every 10 days

Medtronic
Guardian Sensor 3

Eversense
Change Implant every 3 months
Reattach patch daily
Is Implantable CGM the Future?

- **Advantages:** Accuracy, physical stability, ease of use.
- **Disadvantages:** Currently replaced every 3 months, requires meter calibration, tetracycline antibiotic interaction
Insulin Pumps
Multiple Daily Injections vs. Insulin Pump

A. Multiple Daily Insulin Injections

- Rapid-acting insulin injection
- Long-acting insulin injection

Wide swings in blood glucose
High mean blood glucose = high glycated hemoglobin
Nighttime hypoglycemia
Marked dawn phenomenon

B. Insulin-Pump Therapy

- Insulin Delivery
  - Mealtime bolus
  - Square-wave bolus for fatty meal
  - Constant basal rate

- Blood Glucose (mmol/liter)
- Decreased glycemic variability and hypoglycemia
- Lowered mean blood glucose and glycated hemoglobin
Who needs an Insulin Pump?

Diabetes Control and Complications Trial
(began enrollment in 1983)

A more than 180 mg per deciliter (10 mmol per liter), a weekly 3 a.m. measurement greater than 65 mg per deciliter (3.6 mmol per liter), and hemoglobin A1c (glycosylated hemoglobin), measured monthly, within the normal range (less than 6.05 percent). The patients initially chose either multiple injections or pump therapy and could subsequently change to the other method if their glycemic goals were not achieved or if such was their preference. The patients in
Insulin Pumps
Do I have Everything?!

• Tube Pump: Pump is attached to child

• Tubeless Pump: Need to keep track of controlling device

• Tip: If something falls off and you aren’t 100% confident, don’t throw it away.
Original Omnipod vs. Dash

Original Omnipod

Pod + PDM + Meter

Phone (display only)

Omnipod Dash

Pod + PDM + Meter

Phone (display only)
Integrated Pumps/Sensors
Medtronic 670G and Tandem Control-iQ
Limitations of Integrated Pump/Sensor Technology

- *Minimum* requirement that patient wear a fully functioning pump *and* glucose sensor at all times.
- Is not an “artificial pancreas”
- Potential for patient to spend more time with technological trouble shooting
### Percentile Comparison

- 25-75%
- 0-60%

---

### Hypoglycemic Patterns (4)**

<table>
<thead>
<tr>
<th>Pattern</th>
<th>Time</th>
<th>Occurrences</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>7:20 AM - 10:35 AM</td>
<td>4</td>
</tr>
<tr>
<td>2</td>
<td>12:33 PM - 2:04 PM</td>
<td>3</td>
</tr>
<tr>
<td>3</td>
<td>12:05 AM - 12:40 AM</td>
<td>1</td>
</tr>
</tbody>
</table>

** Only highest priority shown.

### Hyperglycemic Patterns (2)

<table>
<thead>
<tr>
<th>Pattern</th>
<th>Time</th>
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</thead>
<tbody>
<tr>
<td>4</td>
<td>3:20 PM - 5:30 PM</td>
</tr>
<tr>
<td>5</td>
<td>11:05 AM - 11:55 AM</td>
</tr>
</tbody>
</table>

### Auto Mode Exit Analysis

<table>
<thead>
<tr>
<th>Reason</th>
<th>A</th>
<th>B</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Calibration</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>High SG Auto Mode Exit</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Auto Mode max delivery</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Auto Mode min delivery</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>BG required for Auto Mode</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Sensor Algorithm Underread</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>Sensor Updating</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>No SG values</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Sensor Expired</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Auto Mode disabled by user</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Alarms</td>
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<td>0</td>
</tr>
<tr>
<td>Pump Suspend by user</td>
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<td>0</td>
</tr>
<tr>
<td>Auto Mode Warm Up</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Unidentified</td>
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<td>0</td>
</tr>
</tbody>
</table>

### Statistics

- **Auto Mode (per week):** 63% (4d 9thh)
- **Manual Mode (per week):** 37% (2d 1sth)
- **Sensor Wear (per week):** 63% (4d 9thh)
- **Average SG ± SD:** 152 ± 55 mg/dL
- **Average BG:** 148 ± 67 mg/dL
- **Bo/Calibration (per day):** 7.7 / 2.1
- **Total daily dose (per day):** 35 units
- **Bolus amount (per day):** 15U (43%)
- **Auto Basal / Basal amount (per day):** 20U (57%)
- **Set Change:** Every 6.0 days
- **Reservoir Change:** Every 6.0 days
- **Meal (per day):** 4.2
- **Carbs entered (per day):** 173 ± 57 g
- **Active Insulin time:** 2.45 hrs
Closed-Loop Pump + Sensor

- Significantly more time in range in the closed-loop group
- Not perfect: Average A1c reduction of 0.3%, with 7% of patients in closed-loop group seeing increase in their A1c
- Same technology limits apply: DKA occurred in a closed-loop participant due to bad site

NEJM 2019; 381:1707-17.
Closed-Loop Pump + Sensor

Glycated Hemoglobin (%)

26 Week

Baseline

NEJM 2019; 381:1707-17.
Closed-Loop Pump + Sensor

Time below 70 mg/dL

NEJM 2019; 381:1707-17.
More Flexible Device Interaction in the Future?

- Alternate controller enabled (ACE) insulin pump: Ability to interact with different devices that meet FDA “special controls” standards

FDA authorizes first interoperable insulin pump intended to allow patients to customize treatment through their individual diabetes management devices

For Immediate Release: February 14, 2019
Do-it-yourself Artificial Pancreas?
FDA Warns People with Diabetes and Health Care Providers Against the Use of Devices for Diabetes Management Not Authorized for Sale in the United States: FDA Safety Communication

Date Issued:
May 17, 2019
Diabetes Technology

3rd Annual Sweet Science Conference
Myrtle Beach, SC
March 14, 2020
B. Adam Dennis, MD